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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Otto E. Anderhub

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,668	Applicant(s) ANDERHUB ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-27,31-50,52-65 and 87-106 is/are pending in the application.
- 4a) Of the above claim(s) 91-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,6-27,31-50,52-65,87-90 and 95-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed 8 January 2010.

Response to Amendment

The 112, second paragraph rejections to Claims 57 and 58 are withdrawn in light of Applicant's amendments.

The 103 rejections under Cohen'945 in view of Krzyzanowski'085 to independent claims 1, 26 and 50 and their dependent claims is withdrawn in light of Applicant's statement showing that the subject matter of the Cohen'945 reference and the present invention were commonly owned at the time the invention was made.

Response to Arguments

Applicant's arguments filed 8 January 2010 have been fully considered but they are not persuasive.

Applicant argues that Claims 91-94 should be considered because Claims 91-94 are not distinct inventions from Claims 1, 11, 26, 35 and 50. Notwithstanding, Claim 91 is drawn to a distinct *embodiment* that is mutually exclusive from the previously claimed embodiment in Claims 1, 11, 26, 35 and 50. In Claim 91, the protrusion/groove on the cutting portion engages with a protrusion/groove on the storage portion. In independent Claims 1, 11, 26, 35 and 50 the grooves/protrusions on the cutter and storage portion engage with protrusions/grooves on the holder. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of

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such species. In addition, these species are not obvious variants of each other based on the current record. There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. As such, the election by original presentation requirement is maintained and the claims are withdrawn from consideration.

Applicant's arguments regarding the 103 rejection to independent claims 1 and 26 under Krzyzanowski in view of Caisley, state that it would not be obvious to modify the groove of Krzyzanowski to receive the sample holder of Caisley because the groove 27 in Krzyzanowski could not receive Caisley's sample holder. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Independent claim 50 was rejected under 103 in view of Krzyzanowski in view of Caisley in view of Slater. Applicant made similar arguments regarding the combination of Krzyzanowski in view of Caisley. The same arguments above apply, however a new grounds of rejection is below in light of Applicant's amendment.

Applicant argues that new independent claims 11 and 35, which were amended to become independent claims but contain no substantial differences, are not obvious because Kryzanowski teaches the advantage to using plastics, rather than metals in surgical tools. However, in the background, Kryzanowski teaches that the use of metals in biopsy jaw assemblies is old and well known. Although plastics may be advantageous for the reasons discussed by Kryzanowski, constructing a known object out of metal does not constitute a patentable difference over the prior art.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1, 2, 6-11, 13-15, 17-27, 31-35, 37-49, 95, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krzyzanowski (US Patent 6,440,085) in view of Caisley (WO 02/39810).

Claims 1, 2, 6, 13, 14, 15, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 37, 38, 39, 41, 42, 43, 44, 45, 46, 47 48, 49, 95, 96, : Krzyzanowski'085 teaches a biopsy device with an end effector that contain a first jaw (30) and a jaw assembly having a holder (26) pivotally connected to the first jaw having a cutting portion (27). The holder contains a groove for receiving a protrusion on the cutter (the groove is unlabeled but can best be seen in Figure 7 in light of Figures 3 and 4). Krzyzanowski'085 teaches that the jaw is configured to store a sample because of its intended use and cup-shape.

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Krzyzanowski'085 further teaches actuating wires (24) extending through an elongate member (12).

Krzyzanowski'085 does not teach a removable storage portion having a protrusion that is received by a groove on the holder.

Caisley'801 teaches a sample collection container (1) that is attached to a holder (Figure 3) with a protrusion (shown clearly, but labeled in Figure 1b) that engages a groove (17; page 9, line 11 to page 10, line 20) on the holder base in order to create a removable storage container for the sample. It would be obvious to one of ordinary skill in the art to modify the device of Krzyzanowski'085 with a removable sample container, as taught by Caisley'801 in order to provide an easy way to capture the entire sample after it is taken from the patient.

Claims 7, 8, 9, 10, 31, 32, 33, 34, 35: Krzyzanowski'085 in view of Caisley'801 discloses or makes obvious the invention as claimed with the exception the materials of the different components.

Regarding the material of the different components, the examiner contends that this is nothing more than an obvious design choice. Cutting edges were previously known as being manufactured out of plastic or metal. Forming two removable components out of different materials would allow for one material to be sharpened and the other material to be less expensive, for example.

Claim 12, 16, 36, 40, 87 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krzyzanowski'085 in view of Caisley'801, as applied to Claim 1 and 26 respectively, further in view of Slater et al. (US Patent 5,482,054).

Claim 12, 36: Krzyanowski'085 in view of Caisley'801 teach the limitations of Claims 12 and 36 except for a holder and cutting portion on the first jaw.

Slater'054 teaches that it is known to provide both a first and second jaw with a cutter and holder in order to provide an additional cutting surface for cutting tissue. It would have been obvious to one of ordinary skill in the art to modify the device of Krzyanowski'085 in view of Caisley'801 with a second cutter and holder, as taught by Slater'054 so that it too has this advantage.

Claim 16, 40: Krzyanowski'085 in view of Caisley'801 teach the limitations of Claims 16 and 40 except for a non-straight portion connecting a tang to a cutting edge.

Slater'054 shows that it is known to connect a cutter (418; Figure 8b) with a non-straight portion (portion of 418 between 30 and cutting element 20 in Figure 8b) to a tang (proximal end of element 418 surrounding openings 66 and 419) to a cutting edge (20) that is configured to be received in a gap in the holder (Figures 8a-8c). The claim would have been obvious because the known technique using a tang and non-straight connector portion to place a cutting element in a jaw was recognized as part of the ordinary capabilities of one skilled in the art.

Claims 87, 88: : The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66).

Claims 50, 52-65, 89, 90, 97-103 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krzyanowski'085 in view of Caisley'801 in view of Slater et al. (US Patent 5,482,054).

Claim 104 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krzyzanowski'085 in view of Caisley'801, as applied to Claim 1 and 26 respectively, further in view of Slater'054.

Claim 50, 52, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 89, 102, 103, 104, 105:

Krzyzanowski'085 teaches a biopsy device with an end effector that contain a first jaw (30) and a jaw assembly having a holder (26) pivotally connected to the first jaw having a cutting portion (27). The holder contains a groove for receiving a protrusion on the cutter (the groove is unlabeled but can best be seen in Figure 7 in light of Figures 3 and 4). Krzyzanowski'085 teaches that the jaw is configured to store a sample because of its intended use and cup-shape.

Krzyzanowski'085 does not teach a removable storage portion having a protrusion that is received by a groove on the holder.

Caisley'801 teaches a sample collection container (1) that is attached to a holder (Figure 3) with a protrusion (shown clearly, but labeled in Figure 1b) that engages a groove (17; page 9, line 11 to page 10, line 20) on the holder base in order to create a removable storage container for the sample. It would be obvious to one of ordinary skill in the art to modify the device of Krzyzanowski'085 with a removable sample container, as taught by Caisley'801 in order to provide an easy way to capture the entire sample after it is taken from the patient.

Krzyzanowski'085 in view of Caisley'801 do not teach a non-straight portion connecting a tang to a cutting edge.

Slater'054 shows that it is known to connect a cutter (418; Figure 8b) with a non-straight portion (portion of 418 between 30 and cutting element 20 in Figure 8b) to a tang (proximal end of element 418 surrounding openings 66 and 419) to a cutting edge (20) that is configured to be received in a gap in the holder (Figures 8a-8c). The claim would have been obvious because the known technique using a tang and non-straight connector portion to place a cutting element in a jaw was recognized as part of the ordinary capabilities of one skilled in the art.

Regarding the limitation that the groove is located closer to the bottom of the holder than to the top of the holder, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to locate the groove closer to the bottom of the holder than to the top of the holder because Applicant has not disclosed that locating the groove closer to the bottom of the holder than to the top of the holder provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the invention of Krzyzanowski'085 in view of Caisley'801 in view of Slater'054, and applicant's invention, to perform equally well with either the groove located towards the top of the holder, as disclosed by modified Krzyzanowski'085 or with the groove towards the bottom of the holder, as claimed because locations would perform the same function of holding the blade for use on a patient.

Claim 53, 54, 55, 106: Cohen'945 in view of Krzyzanowski'085 discloses or makes obvious the invention as claimed with the exception of the materials of the different components.

Regarding the material of the different components, the examiner contends that this is nothing more than an obvious design choice. Cutting edges were previously known as being manufactured out of plastic or metal. Forming two removable components out of different materials would allow for one material to be sharpened and the other material to be less expensive, for example.

Claim 90: The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66).

Claim 97, 98: The non-straight portion of Slater'054 is a substantially vertical wall that is substantially orthogonal to a plane of a sample hole on the second end effector.

Claim 99: Slater'054 shows that the holder (518) has a bridging portion (region between bore 30 on the holder 518). In light of the rejection to Claim 50 above, it would be obvious to use a similar connection structure to attach the holder to the cutter.

Claim 100, 101: The tang of Slater'054 contains a pivot bore (30) and an actuator hole (66). Slater'054 further shows that the bores/holes are aligned (Figure 8a).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/L. B./

Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734